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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Washington, D.C. 20231

OIPE JC19 FEB 04 2002 PATENT & TRADEMARK OFFICE

In re PATENT APPLICATION of
Inventors: **Guenther**
Appln. No.: **09/811,361**
Filed: **March 16, 2001**
Title: **Transgenic Mice Containing Retina-Specific Nuclear Hormone Receptor Gene Disruptions**

Group Art Unit: **1633**
Examiner: **Qian, Celine X.**
Docket/Order #. **R-125**
Deposit Acct **50-1271**
Customer # **26619**

Date: **February 4, 2002**

RESPONSE TO RESTRICTION REQUIREMENT TRANSMITTAL

Sir:

Please file the enclosed response in the above-identified application. The signature below is to be treated as the signature to the enclosure in absence of a signature thereto.

FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity previously claimed	Claims remaining	Highest # paid for		Present Extra	Small Entity	Add'l Fee	Fee Code
2. Total Claims	30	minus	47 =	**0**	x $9. =	+ **0**	203
3. Independent Claims	16	minus	16 =	**0**	x 42. =	+ **0**	202
4. If amendment enters multiple dependent claim(s) for the first..... add					+ $140. =	+	204
5. Original due date: January 3, 2002							
6. **Petition is hereby made** to extend the due date to cover the date this response is filed, for which the requisite fee is enclosed							215 216 217
7. Enter any previous extension fee paid and (subtract)						-	
8. Total fee for extension of time:						**+$ 55.00**	
9. If Terminal Disclaimer is enclosed, add Rule 20(d) official fee.....					+ $55. =	+	248
10. If IDS enclosed requires Official Fee, ... add or if Rule 97(d) Petition, ... add					+ $240. = + $130. =	+ +	126 122
11. After-Final Request Fee per Rules 129(a) and 17(r).....					+ $355. =	+	246
12. No. of additional inventions for examination per Rule 129(b):.....		ea			x $355. =	+	249
13. Petition fee for						+	
TOTAL FEE: ☒ **CHARGE AUTHORIZATION** ☐ **ENCLOSED** =						**$ 55.00**	

Charge Statement: The Commissioner is hereby authorized to charge any missing or insufficient fees relative to this application, or credit any overpayment, to our Account/Order Nos. above, for which purpose a duplicate copy of this sheet is enclosed.

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I certify that this paper and listed enclosures are being deposited with the U.S. Postal Service as "Express Mail Post Office to Addressee" under 37 CFR 1.10 on above date, addressed to the Commissioner for Patents, BOX AMENDMENT, Washington, D.C. 20231

Joyce Vogel

#11/308
2/15/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: CATHERINE GUENTHER

Serial No.: 09/811,361

Filed: March 16, 2001

Group Art Unit: 1633

Examiner: Qian, Celine X.

Attorney Docket No.: R-125

For: TRANSGENIC MICE CONTAINING RETINA-SPECIFIC NUCLEAR RECEPTOR GENE DISRUPTIONS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed December 03, 2001, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, Invention I (claims 1-10 and 17-21), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a retina specific nuclear receptor gene, a retina specific nuclear receptor gene knockout non-human animal and a method of making said non-human animal.

In the restriction, the Examiner asserts that claims 1-37 are drawn to six distinct subjects, grouped as: Invention I (claims 1-10 and 17-21), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a retina specific nuclear receptor gene, a retina specific nuclear receptor gene knockout non-human animal and a method of making said non-human animal; Invention II (claims 11, 13, 29, 30, 33 and 34), drawn to a method of identifying an agent that modulates retina-specific nuclear receptor gene expression; Invention III (claims 12, 14, 35 and 36), drawn to a method of identifying an agent that modulates retina-specific nuclear receptor gene function; Invention IV (claim 16), drawn to an agent that modulates retina-specific nuclear receptor gene expression or function; Invention V (claims 25-28, 31 and 32), drawn to a method of identifying an agent that ameliorates an eye abnormality; and Invention VI (claim 37), drawn to an agent that modulates retina-specific nuclear receptor gene expression/function or ameliorates eye abnormality. The Examiner also

asserts that claim 15 is generic to groups II and III. Applicants respectfully request reconsideration and withdrawal of the requirement.

Applicants respectfully draw the Examiner's attention to claims 22-24 of the instant application. These claims have not been included in the current Restriction Requirement.

Specifically, the Examiner asserts that the claims of Invention I are materially different from the claims of Invention II and are thus patentably distinct inventions. The Applicants disagree with the Examiner's conclusion in that the claims of Invention I are related to the methods recited in the claims of Invention II and thus would not require a separate search or examination that would seriously burden the Examiner.

The Examiner further asserts that the claims of Invention I and Invention III are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods of identifying agents that modulate function of a retina-specific nuclear receptor gene recited in the claims of Invention III and the claims of Invention I are related. Thus, a separate search or examination of these claims would not seriously burden the Examiner.

The Examiner also asserts that the claims of Invention I are patentably distinct as the inventions are drawn to materially different compositions and methods that are not directly related to the claims of Invention IV. The Applicants disagree with the Examiner's conclusion in that the agents that modulate retina-specific nuclear receptor gene expression or function recited in the claims of Invention IV and the claims of Invention I are related. A separate search or examination on these claims can be made without serious burden to the Examiner.

It is also asserted by the Examiner that the claims of Invention I and Invention V are patentably distinct as the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods of identifying agents that ameliorate or modulate an eye abnormality recited in the claim of Invention V and the claims of Invention I are related. A search and examination of these claims can therefore be made without serious burden on the Examiner.

According to the Examiner, claims of Invention I and the claims of Invention VI are patentably distinct because the inventions are drawn to materially different compositions and

methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention VI are related to the claims of Invention I. Thus, a separate search and examination of these claims can be made without serious burden on the Examiner.

The Examiner further asserts that the claims of Invention II and Invention III are patentably distinct as the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention II and the methods recited in the claims of Invention III both require the same or related starting materials. More particularly, claims 11 and 29-30 of Invention II and claim 12 of Invention III both require that a non-human transgenic animal comprising a disruption in a retina-specific nuclear receptor gene be provided. The claims also recite modulation of the gene by an agent. Any search or examination of the prior art conducted on these aspects, *i.e.* a non-human transgenic animal comprising a disruption in a retina-specific nuclear receptor and modulation of this gene, would produce results that would comprise modulation of the expression or modulation of the function of a retina-specific nuclear receptor gene. The same applies to claim 13 of Invention II and claim 14 of Invention III as directed to cells and the modulation of the expression and function of a retina-specific nuclear receptor.

Both claims 33 and 34 of Invention II and claims 35 and 36 of Invention III require cells comprising a disruption in a retina-specific nuclear receptor. In addition, both groups of claims are directed to methods of identifying agents that modulate a retina-specific nuclear receptor gene. Furthermore, both groups of claims are directed to agents that modulate a phenotype associated with a disruption in a retina-specific nuclear receptor gene. Therefore, any search or examination of the prior art conducted on these aspects, *i.e.* a cell comprising a disruption in a retina-specific nuclear receptor gene and methods of identifying agents that modulate a phenotype associated with a disruption in a retina-specific nuclear receptor gene, would produce results that would comprise modulation of the expression or modulation of the function of a retina-specific nuclear receptor gene, wherein a phenotype associated with a disruption of a retina-specific nuclear receptor gene is modulated. Thus, a search and examination of the claims of Inventions II and III can be made without serious burden on the Examiner.

The Examiner further contends that the claims of Invention II are patentably distinct from the claims of Invention IV as the agent recited in the claims of Invention IV can be identified by

other methods. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV are related to the methods of Invention II. Thus, a search and examination of these claims can be made without serious burden to the Examiner.

The Examiner also asserts that Inventions II and V are patentably distinct because the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion. Specifically, the methods of Invention II require the same or related starting materials as the methods of Invention V. More particularly, both groups of claims recite administering an agent to a transgenic mouse comprising a disruption in a modulation of the expression or modulation of the function of a retina-specific nuclear receptor gene. Further, the methods recited in claims 29-30 and 33-34 of Invention II comprise the step of determining whether the agent modulates retina-specific nuclear receptor gene expression, wherein the agent modulates a phenotype associated with a disruption in a retina-specific nuclear receptor gene. This aspect of claims 29-30 and 33-34 of Invention II is closely related to the methods comprising identifying agents that ameliorate/modulate a phenotype recited in claims 25 and 31-32 of Invention V. Therefore, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further concludes that the claims of Invention II are patentably distinct from the claims of Invention VI because the inventions are drawn to methods and compositions that are not directly related. The Applicants disagree with this conclusion in that the method of identifying an agent comprising the step of determining whether the agent modulates retina-specific nuclear receptor gene expression, wherein the agent modulates a phenotype associated with a disruption in a retina-specific nuclear receptor gene recited in Invention II can produce an agent of Invention VI. Further, Applicants assert that a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner also asserts that the claims of Invention III are patentably distinct from the claims of Invention IV as the agents recited in the claims of Invention IV can be made by another and materially different process. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV are related to the methods recited in the claims of Invention III. Thus, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further asserts that Inventions III and V are patentably distinct because the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention III and the methods recited in the claims of Invention V both require the same or similar starting materials. Further, the claims of Invention III and Invention V are drawn to methods of identifying agents that modulates a retina-specific nuclear receptor gene, in which the steps or modes of operation of determining whether the agent modulates a retina-specific nuclear receptor gene are the same or closely related. For example, to both groups of claims recite modulation of a phenotype. In the case of claims 36 of Invention III and claims 25 and 31 of Invention V, eye abnormality is recited. Therefore, a search or examination of the prior art would reveal results having modulation of any phenotype, including eye abnormalities. Thus, a search and examination of claims of Inventions III and V can be made without serious burden on the Examiner.

The Examiner also asserts that the claims of Invention III are patentably distinct from the claims of Invention VI because the inventions are drawn to methods and compositions that are not directly related and that the methods of Invention III cannot produce the agents of Invention VI. The Applicants disagree with this conclusion in that the method of identifying an agent comprising the step of determining whether the agent modulates retina-specific nuclear receptor gene function, wherein the agent modulates a phenotype associated with a disruption in a retina-specific nuclear receptor gene recited in Invention III can produce an agent of Invention VI. Therefore, the methods recited in the claims of Invention III are related to the agents recited in the claims of Invention VI and that a search and examination of these claims can be made without serious burden to the Examiner.

As asserted by the Examiner, the claims of Invention IV are patentably distinct from the claims of Invention V because the inventions are drawn to compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV are related to the methods recited in the claims of Invention V and thus, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further asserts that Inventions IV and VI are patentably distinct as the inventions are drawn to materially distinct compositions. Applicants disagree with the

Examiner's assertion in that the claims of Inventions IV and VI are related and a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner also concludes that the claims of Invention V are patentably distinct from the claims of Invention VI because the agents of Invention V can be identified by methods other than those recited in Invention VI. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention VI and the methods recited in the claims of Invention V are related and a search and examination on these claims can be made without serious burden to the Examiner.

Although Applicants have provisionally elected Group I for purposes of advancing prosecution of the present application, Applicants contend, for the foregoing reasons, that the restriction requirement is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of the requirement.

Applicants would also like to draw the Examiner's attention to claims 22-24 of the instant application. These claims have not been included in the current Restriction Requirement and clarification as to these claims is requested.

A Petition for the Extension of Time for response to the Office Action for a period of one month from January 3, 2002 up to and including February 4, 2002 is submitted concurrently herewith.

Respectfully submitted,

Date: February 4, 2002

Mariette A. Lapiz

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Enclosures